

- II. Claims 37-62, 84, 123-148, and 170, drawn to a polypeptide and composition.
- III. Claims 63-64 and 149-150, drawn to an antibody or antisera.
- IV. Claims 65-66 and 151-152, drawn to a method of producing a polypeptide.
- V. Claims 67-68 and 153-154, drawn to a method of inducing proliferation of T-cells.
- VI. Claims 69-70 and 155-156, drawn to a method of inducing production of IFN-gamma in T-lymphocytes.
- VII. Claims 71-72, 77-78, 81, 157-158, 163-164, and 167, drawn to a method for making a modified or recombinant nucleic acid.
- VIII. Claims 73-74, 79-80, 159-160, and 165-166, drawn to a nucleic acid library and composition.
- IX. Claims 173-180, drawn to a computer readable medium.
- X. Claims 181-183, drawn to a method of using a computer system to present information.

Office Action, pp. 2-3.

The Examiner finds that each of the above-identified ten Claim Groups reads on patentably distinct species. For an elected Group drawn to amino acid/polypeptide sequences, the Examiner specifies that Applicants must further elect a single amino acid/polypeptide sequence. For an elected Group drawn to nucleotide sequences, the Applicants must further elect a single nucleic acid sequence.

Applicants respectfully traverse the restriction requirement because the Examiner has required a further sequence restriction of a claim drawn to several amino acid sequences or nucleic acid sequences to only one amino acid or nucleic acid sequence, respectively.

In explaining this restriction limiting examination to only one sequence, the Examiner states that "[it] is noted that the multitude of sequence submissions for examination has resulted in undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement." Office Action, page 4. In further support of this sequence election requirement, the Examiner presents a paragraph allegedly taken verbatim from MPEP § 803.04 which includes the following two sentences: "Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a specie [sic] election requirement." *Id.*

Applicants were unable to locate these two specific sentences or a provision that only one sequence is to be examined in § 803.04 of the current edition of the MPEP (8th ed. August 2001). Nor were Applicants able to locate this single sequence election restriction requirement on the USPTO's website or in the current edition of the MPEP posted on the USPTO's website.

Applicants respectfully submit that this single sequence election restriction requirement is improper, as the MPEP specifically provides that *ten sequences constitute a reasonable number for examination purposes*. Section 803.04 of the MPEP (8th ed. August 2001) expressly states:

Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq.* and *permit a reasonable number of such nucleotide sequences to be claimed in a single application. It has been determined that normally ten sequences constitute a reasonable number for examination purposes.* Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably distinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

MPEP § 803.04 (emphasis added). Applicants respectfully traverse the sequence election restriction requirement in view of the express guidelines set forth by the Commissioner and outlined in the MPEP.

Moreover, Applicants respectfully traverse this sequence election requirement because it requires restriction between a single claim, which is legally improper. As stated by the CCPA:

As a general proposition, an applicant has a right to have *each claim* examined on the merits.

* * *

If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

* * *

It is apparent that §121 provides the Commissioner with the authority to promulgate rules designed to *restrict an application* to one of several claimed inventions . . . It does not, however, provide a basis for an examiner acting under the authority of the Commissioner to *reject* a particular *claim* on that same basis.

* * *

We hold that a rejection under §121 violates the basic right of the applicant to claim his invention as he chooses.

In re Weber, Soder and Boksay, 198 USPQ 328, 331-332 (CCPA 1978) (emphasis in original and emphasis added) [hereinafter referred to as "*In re Weber*"]. See also *In re Haas*, 179 USPQ 623, 624-625 (CCPA 1973) (hereinafter referred to as *In re Haas I*); *In re Haas*, 198 USPQ 328,

334-337 (CCPA 1978) (hereinafter referred to as *In re Haas II*). Thus, the CCPA ruled that the statute authorizing restriction practice, *i.e.*, 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See In re Weber, In re Haas I, and In re Haas II*. Indeed, the CCPA unequivocally stated that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *In re Weber*:

So the discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-- no matter how broad, which means no matter how many independently patentable inventions may fall within it.

In re Weber, 198 USPQ at 334.

As the case law clearly demonstrates, restriction within a single claim is legally improper. An inventor has clear constitutional and statutory rights to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. § 112 are satisfied. *See, e.g.*, MPEP § 803.02; *In re Wolfrum* 179 USPQ 620 (CCPA 1973); *In re Kuehl* 177 U.S.P.Q. 250 (CCPA 1973).

For at least the foregoing reasons, Applicants respectfully submit that the sequence election restriction requirement is improper and request that it be withdrawn.

In the event that the sequence election restriction requirement is maintained, Applicants provisionally elect Claim Group II and the polypeptide sequence identified as SEQ ID NO:8 with traverse.

Applicants specifically reserve the right to pursue any non-elected claims and/or sequences in one or more continuation and/or divisional applications. Applicants expressly reserve the right to appeal this decision to the Board of Appeals and/or the federal courts in the event the restriction requirement is made final.

Conclusion.

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an